UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Karen Williams Magistrate Judge Honorable Thomas Vanaskie (Ret.), Special Discovery Master **ORDER GRANTING IN PART AND DENYING IN PART MOTION TO SEAL PURSUANT TO L.CIV.R. 5.3**

THIS MATTER is before the Court by way of Plaintiff's challenge to the confidentiality designation of an email and deposition testimony of Min Li, Ph.D., relating to that email, as well as by way of the "Motion to Redact and Seal Portions of the Hearing Transcript of September 10, 2021 Pursuant to Local Civil Rule 5.3(g)" (ECF No. 1584[1]) filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Prinston Pharmaceutical Inc. ("Prinston"), Huahai U.S. Inc. ("Huahai U.S."), and Solco Healthcare US, LLC ("Solco," and collectively with ZHP and Prinston, "the ZHP Parties") on notice to liaison counsel for Plaintiffs; and having carefully considered the question of whether sealing of these documents is warranted given the requirements of the applicable case law and the factors contained in Local Civil Rule 5.3(c)(2); and the standards set forth therein having been found to have been met only to a portion of the email, but not as to Dr. Li's deposition testimony and not as to the September 10, 2021 hearing transcript, the following Findings are made:

FINDINGS

1. As noted in the Order of May 24, 2021 (ECF No. 1269) granting in part an earlier ZHP motion to seal documents (ECF No. 859), the parties to this Multi District Litigation arising out of the alleged contamination of blood pressure medication negotiated the terms of an agreed-upon order to maintain the

[1] Throughout this Order, the designation "ECF No. ___" shall refer to the document number of a particular filing in the Court's ECF system.

confidentiality of any materials so designated by a party. On June 26, 2019, the Honorable Robert B. Kugler entered the agreed-upon self-executing "Confidentiality and Protective Order" (the "Protective Order") (ECF No. 139).

2. The Protective Order permits the producing party to safeguard information by designating a document either "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION." If a document does not contain one of these designations, then the information contained therein may be considered publicly accessible.

3. The Protective Order defines the type of information that warrants a confidentiality designation:

> The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.
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> "RESTRICTED CONFIDENTIAL INFORMATION" means Documents that a Party has designated as "RESTRICTED CONFIDENTIAL" in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans;

> trade secrets; customer lists; pricing; market share; product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm. . . .

(ECF No. 139, ¶¶ 9(B), (M).)

4. Recognizing that in a case of this nature, complexity, and business sensitivity, liberal designation of documents as confidential is anticipated, the Protective Order states that "nothing herein shall be construed to prevent a Producing Party from designating documents as 'CONFIDENTIAL INFORMATION' in order to expedite the flow of discovery and to facilitate discovery. . . ." (*Id.* ¶ 9(B)).

5. Pursuant to the Protective Order a party may designate a document as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. *Id.* ¶¶ 22, 24. Disclosure of information designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" other than in accordance with the Order may subject the disclosing person to sanctions. *Id.* ¶ 26.

6. Pursuant to the Protective Order, the ZHP Parties designated as "Restricted Confidential Information" a July 27, 2017 email authored by Jinsheng Lin that he sent to a number of individuals. Dr. Li, one of the intended recipients of the July 27, 2017 email, was questioned about the email during his April 20, 2021 deposition. The email was also discussed by counsel during the hearing held on

September 10, 2021 on Plaintiffs' motion to compel additional discovery. The ZHP Parties seek to maintain under seal the July 27, 2017 email and approximately twenty-two (22) pages of the transcript of Dr. Li's deposition testimony, and to redact those parts of the September 10, 2021 hearing transcript that concern the July 27, 2017 email.

7. The Protective Order provides that the "portions of any . . . hearing transcript taken in the Litigation, wherein the Documents themselves, or the contents of the Documents, designated as PROTECTED INFORMATION are identified, discussed, or disclosed, shall also be designated as PROTECTED INFORMATION and shall be subject to the terms of this Protective Order." *Id*. at ¶ 17(B).

8. The Protective Order establishes the procedures to be followed when material designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" is submitted as part of a court filing. Specifically, the Protective Order provides that "[w]here the filing party has not had an opportunity to confer with the Producing Party, in advance of a filing, the filing party shall not attach materials containing 'PROTECTED INFORMATION' to its filing but shall instead designate by Bates number the materials containing 'PROTECTED INFORMATION' that would have been attached or completely redact all 'PROTECTED INFORMATION' from such materials." *Id.* The Protective Order then requires the filing and producing parties to confer "to determine whether they can agree upon non-confidential redacted or excerpted pages of materials containing 'PROTECTED INFORMATION' to attach to the filing in place of the

Bates number designations or redacted materials." *Id.* If the parties are unable to agree, "the designating party must file a motion to seal the materials containing 'PROTECTED INFORMATION' pursuant to the requirements for doing so as set forth in Local Rule 5.3(c), and within thirty (30) days of the completion of briefing related to the original motion, or else waive confidentiality as to the materials containing 'PROTECTED INFORMATION' at issue." *Id.*

9. The parties have complied with the requirements of Local Rule 5.3. Specifically, the ZHP Parties have submitted an index, as required by Local Rule 5.3(c), identifying the material to be sealed, the basis for sealing, the purported injury that may result if sealing is denied, why a less restrictive alternative to sealing is not appropriate, and the bases for Plaintiffs' opposition to sealing. (Ex. B to Bonner Declaration, ECF No. 1584-6.) Also submitted in support of the Motion to Seal is the Declaration of Dr. Li. (ECF No. 1584-5.)

10. The Third Circuit has identified the following as a non-exhaustive and non-mandatory list of factors to consider when deciding a motion to seal:

a. Whether disclosure would violate any privacy interests;

b. whether the information is being sought for a legitimate purpose or for an improper purpose;

c. whether disclosure would cause a party embarrassment;

d. whether confidentiality is being sought over information important to public health and safety;

e. whether the sharing of information among litigants will promote fairness and efficiency;

f. whether a party benefitting from the order of confidentiality is a public entity or official; and

g. whether the case involves issues important to the public.

In re Avandia Mktg., Sales Practices and Products Liab. Litig., 924 F.3d 662, 670 (3d Cir. 2019) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3 476, 483 (3d Cir. 1995).

11. The foregoing factors are applied in the context of materials that are not part of the "court record." However, a "more rigorous common law right of access" applies when, as here, the discovery materials are filed with the court. *Avandia*, 924 F.3d at 670. "In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access." *Id.* (citing *Goldstein v. Forbes* (*In re Cendant Corp.*), 260 F.3d 183, 192–93 (3d Cir. 2001).

12. "Analytically distinct from the District Court's ability to protect discovery materials under Rule 26(c), the common law presumes that the public has a right of access to judicial materials. In both criminal and civil cases, a common law right of access attaches 'to judicial proceedings and records.'" *In re Avandia*, 924 F.3d at 672.

13. The common law right of access applies to a "judicial record." A "judicial record" is a document that "has been filed with the court . . . or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings." *Avandia*, 924 F.3d at 672. "Once a document becomes a judicial record, a presumption of access attaches." *Id.* The ZHP Parties do not dispute that the July 27, 2017 email and the transcripts in question are "judicial records" in that they are

"relevant to the performance of the judicial function," *i.e.*, resolving discovery disputes, and "useful in the judicial process." *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 484 F. Supp. 3d 249, 259 (E.D. Pa. 2020).

14. "The party seeking to overcome the presumption of access bears the burden of showing 'that the interest in secrecy outweighs the presumption.' The movant must show 'that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking disclosure.'" *Id.*

15. As explained in *Avandia*, 924 F.3d at 672-73 (cleaned up and emphasis added):

> To overcome that strong presumption, the District Court must articulate the compelling, countervailing interests to be protected, make specific findings on the record concerning the effects of disclosure, and provide an opportunity for interested third parties to be heard. In delineating the injury to be prevented, specificity is essential. *Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient*. Careful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants. To that end, the District Court must conduct a document-by-document review of the contents of the challenged documents.

16. "[C]oncern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access." *Id*. at 676. Furthermore, "a person's motive for inspecting or copying judicial records is irrelevant under the common law right of access." *Id*. at 677.

17. With respect to access to judicial records in the context of litigation concerning the safety of prescription medication, the Third Circuit has observed:

> [T]he public's right of access must be the starting point, not just one of multiple factors. *The scale is tipped at the outset in favor of access.* And the right of access is not a mere formality – it promotes public confidence in the judicial system; diminishes possibilities for injustice, incompetence, perjury, and fraud; and provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness. *These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug*.
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> *Id.* (emphasis supplied).

18. The July 27, 2017 email, the deposition testimony of Dr. Li concerning this email, and the September 10, 2021 hearing transcript have been reviewed with these principles in mind. Each of the documents will be discussed in turn.

A. July 27, 2017 Email

19. As described in the proposed sealing order submitted by the ZHP Parties as a publicly-accessible document (ECF No. 1584-3), the two-page July 27, 2017 email "was prepared by Jinsheng Lin as part of a project by ZHP to improve its manufacturing processes for irbesartan API[2]—not valsartan –at the research and development stage."

20. As explained in more detail in Dr. Li's Declaration (ECF No. 1584-5), another document filed by the ZHP Parties on the publicly-accessible docket, "[t]he July 27, 2017 email . . . concerns the results of a preliminary investigation by

[2] API is the abbreviation for "Active Pharmaceutical Ingredient," defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." 21 C.F.R. § 207.1.

ZHP's technical analysis department (CEMAT) into certain technical changes observed during the attempted process improvements for the manufacture of irbesartan API." Dr. Li's publicly-available declaration states that "the July 27, 2017 email focuses on proprietary technical improvements that were tested by the Chuannan facility's Technical Department, the Technical Department's communications with CEMAT regarding certain technical changes observed during the process improvements, and CEMAT's analysis for an unknown impurity observed during the attempted process improvement of irbesartan API." According to Dr. Li, "[t]he information disclosed in the July 27, 2017 email is highly confidential, proprietary, and competitively sensitive because it reveals how the ZHP Parties sought to optimize their procedures for manufacturing irbesartan API by addressing certain technical process changes, and the specific tests conducted by CEMAT to investigate these changes. These actions were the result of significant research and development by ZHP and have not been disseminated outside of the company." Dr. Li concludes by asserting that "Disclosure of ZHP's API process optimization strategies and testing methods to ZHP's direct competitors would result in significant competitive harm to the ZHP Parties. . . . Disclosure of ZHP's confidential information would allow ZHP's direct competitors to benefit from and implement ZHP's proprietary research and development information . . ., awarding a significant competitive advantage to the ZHP Parties' competitors."

21. The ZHP Parties are entitled to protection for its testing methods and

product "optimization strategies," but the July 27, 2017 email includes information having nothing to do with such matters. Of particular relevance here is the email's explicit reference to valsartan and a publicly available patent dealing with valsartan.

22. The July 27, 2017 email also contains information that is otherwise in the public domain. For instance, ZHP's valsartan, losartan, and irbesartan were subject to publicly-disclosed recalls for suspected contamination with carcinogenic nitrosamines. *See* FDA's Recall Announcement Regarding ZHP's Valsartan, https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity (last visited Jan. 13, 2022). Moreover, an FDA-issued slide deck entitled "Nitrosamines as Impurities in Drugs; Health Risk and Mitigation Workshop Day 1," contains slides reporting that "NDMA identified as a process related contaminant in Valsartan NDMA may have been present in batches reaching back to 2012 when the synthesis was changed to a process using dimethylformamide (DMF) as solvent and NaNO2 [(sodium nitrite)] as a quenching agent to destroy azide (sodium azide, used for tetrazole synthesis)," and "[a]ll Sartans w[]ith a tetrazole ring system synthesized by this technology [are] expected to be contaminated." (https://www.fda.gov/media/147331/download (last visited Jan. 13, 2022)). The FDA has also issued guidance on testing methodologies to detect N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in valsartan. *See* "Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine

(NDEA) Impurity Assay by GC/MS-Headspace" reported at

https://www.fda.gov/media/117843/download (last visited January 13, 2022).

23. An order sealing a judicial record must be based on "*current* evidence to show how public dissemination of the pertinent materials *now* would cause the competitive harm" the ZHP Parties claim. *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993) (citation omitted). The ZHP Parties do not reconcile their claims of competitive harm from disclosure of the July 27, 2017 email with the publicly available information concerning the process for making valsartan and testing methodologies for detection of the suspected carcinogens of NDMA and NDEA.

24. The only data not shown to be available publicly found in the July 27, 2017 email are the chemical structure and molecular weight of the observed impurity, as well as the possible formation route for the contaminant.

25. Assuming this information has competitive significance, a redacted version of the email can be produced that would not reveal confidential product optimization strategies or testing methodologies. Specifically, the ZHP Parties may redact from the first page of the email the second paragraph of the email, beginning with "We investigated" and including the graph and image of the suspected chemical structure. On the second page of the email, the ZHP Parties may redact the chemical formula and the image of the chemical structure, but none of the text. The redactions afford substantial deference to the ZHP Parties' articulation of feared competitive harm while at the same time giving public access

to the parts of a document that are otherwise within the public domain and may bear on the liability questions presented in this case. It was incumbent upon the ZHP Parties to provide evidence to support specific findings concerning the adverse effects of disclosure, and the ZHP Parties have not presented such evidence. Stated otherwise, the ZHP Parties have not presented evidence of "a clearly defined and serious injury" resulting from disclosure of the July 27, 2017 email as required by *In re Avandia.*

B. Deposition Testimony of Dr. Li

26. Dr. Li was questioned about the July 27, 2017 email during his deposition on April 20, 2021 from page 84, line 12 through page 107, line 14.

27. His testimony essentially confirms the content of the July 27, 2017 email that has been found to not warrant sealing.

28. The ZHP Parties argue that Dr. Li's testimony, along with the July 27, 2017 email, describe "the ZHP Parties' process optimization methods as to the manufacture of irbesartan, including observations as to technical changes observed, and proposed testing to examine and analyze these results," and that "[s]uch information, if disclosed to the ZHP Parties' competitors, could be utilized in their own manufacturing and testing procedures for this product, allowing them to reap the benefits of the ZHP Parties' confidential, proprietary research." (ZHP Supp. Brief, ECF No. 1735 at 14.) But there is nothing specific about "process optimization efforts" in Dr. Li's testimony and he did not describe testing methodologies that are proprietary or outside the public domain. While the ZHP

Parties make conclusory claims of competitive harm, they fail to provide any corroborating evidence.

29. The ZHP Parties also contend that Plaintiffs have not shown a compelling reason why the testimony should not be redacted, pointing out that Plaintiffs are free to use the July 27, 2017 email and Dr. Li's related testimony and there is no urgent public health concern since ZHP's valsartan has been recalled and ZHP is presently barred from exporting its valsartan to the United States. The ZHP Parties' argument disregards the fact that the email and related testimony of Dr. Li are properly regarded as "judicial records." There is thus a presumption of access accorded the email and related testimony, and a party's motivation for providing access to judicial records is not relevant. *See In re Avandia*, 924 F.3d at 677. Accordingly, Dr. Li's testimony concerning the July 27, 2017 email need not be sealed.

C. Transcript of the September 10, 2021 Hearing

30. On September 10, 2021 oral argument was presented by Plaintiffs and the ZHP Parties concerning Plaintiffs' motion to compel additional discovery. This motion was prompted, at least in part, by the ZHP Parties' production of the July 27, 2017 email.[3]

31. Because the July 27, 2017 email was designated as "Restricted Confidential Information" by the ZHP Parties, the hearing was conducted *in camera*.

[3] The motion was granted in part by Special Master Order 54, ECF No. 1753, filed on November 12, 2021.

32. On September 27, 2021, the ZHP Parties moved to redact and seal portions of the transcript of the September 10, 2021 hearing. (ECF No. 1584.) The parts that the ZHP Parties seek to redact appear on pages 10 through 37 of the transcript. The requested redactions are modest, consisting of a few words or lines.

33. It is difficult to conceive how the information sought to be redacted would disclose proprietary or valuable competitive information. For example, the ZHP Parties seek to redact the title given to its product optimization process, but there does not seem to be any need to keep that title confidential or any intrinsic value to that title. Other information sought to be redacted, such as the content of the July 27, 2017 email, has been found to not warrant the protection of a sealing order, or is the characterization of the evidence by Plaintiffs' counsel. While the information in the email and an advocate's counsel's characterization of the evidence may be disconcerting, there is no basis to redact any parts of the September 10th transcript. Accordingly, the motion to redact and seal the transcript of the September 10th hearing (ECF No. 1584) will be denied.

Pursuant to the foregoing Findings and for good cause shown **IT IS on this 13th day of January, 2022**, **HEREBY ORDERED AS FOLLOWS:**

1. The ZHP Parties' Motion to Redact and Seal the Transcript of the September 10, 2021 Hearing (ECF No. 1584) is **DENIED.**
2. Plaintiffs' challenge to the "Restricted Confidential Information" designation of the July 27, 2017 email is sustained in part. The July

27, 2017 email may be redacted only as set forth above.

3. Plaintiffs' challenge to the designation of parts of the transcript of the April 20, 2021 deposition of Dr. Min Li as "Restricted Confidential Information" is sustained.

4. Any objection to this Order shall be filed no later than twenty-one (21) days after entry of this Order.

IT IS FURTHER ORDERED THAT the documents in question shall remain under seal until any objections to this Order are resolved or the time for filing objections has expired.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master